UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKETT NO.
08/466,554			

EXAMINER	
ART UNIT	PAPER NUMBER
	16

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

(1) John Storella (Applicant) (3) Peter Seubert (Inventor)

(2) Jean Duvall (Applicant) (4) PATRICIA DUFFY (EXAMINER)

Date of interview 12 December 1996

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description: _____

Agreement ☐ was reached with respect to some or all of the claims in question. ☒ was not reached.

Claims discussed: All pending

Identification of prior art discussed: NONE

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

See attached for specific

In general discussed enablement and scope rejections under

35USC 112, 1st paragraph.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☒ 1. It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph below has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ 2. Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the substance of the interview unless box 1 above is also checked.

Patricia A. Duffy
Examiner's Signature

PTOL-413 (REV. 2-93)

ORIGINAL FOR INSERTION IN RIGHT HAND FLAP OF FILE WRAPPER

Interview Summary
12 December 1996

Discussion centered on five basic points.

1. The differences between Alzheimer's Disease and the transgeneic animal models of beta-amyloidosis. Discussed the fine point in regard to the lack of neurofibrillary tangles with respect to any existing animal or animal model. Discussed restriction of claims to potentially beta-amyloid deposition or secreting models. Support for this limitation in specification was queried by the examiner. Concurred that the transgeneic animal models were a model for beta-amyloidosis.

2. The ability of the assay to detect smaller samples which would be required in small rodents. Discussed that the claim language requires preadministration sampling, administration of the substance and postadministration sampling in the sample. A temporal sequence is implied by the antecedent basis of the claim with regard to "the non-human animal". Applicants were going to consider both points and potentially supply data showing that the assay is sensitive enough to assay smaller samples than the 100 ul used for human CSF in the specification. Applicants were also providing evidence that the assay can distinguish the transgene from the endogenous peptide in the transgeneic models of beta-amyloidosis.

3. Enablement regarding transgeneic animals will be supported by evidence (i.e. scientific papers to be provided).

4. Evidence regarding the establishment of more than one assay to determine the presence of the AB(x-$\geq$41) commensurate in scope with the assay.

5. Arguments will be presented regarding screening nature of the assay rather than therapeutic with regards to Alzheimer's disease.

Exr. Patricia A. Duffy, Ph.D.